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Forschung & Entwicklung

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Ihre Nachricht vom
Ihre Zeichen

Sachbearbeiter H Thiem
Unsere Zeichen thi

Tag
19th of December 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Name, address, phone and fax number of the applicant

RAUMEDIC AG
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95233 Helmbrechts
D - Germany
Tel.: 0049/9252/359-0
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2. Contact person

Mr. Reiner Thiem
Head of Regulatory Affairs
Hermann-Staudinger-Straße 2
95233 Helmbrechts
D – Germany
Tel.: 0049/9252/359-2782

3. Date of preparation of the summary

December, the 19th 2011

Device #: _____

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4. Name of the device

The **RAUMEDIC® -ICP-TEMP-Monitoring-System** is composed of the following elements:

- NEUROVENT®-TEMP IFD-S
- NEUROVENT®-TEMP IFD-R
- NEUROVENT®-P-TEMP
- ICP-TEMP-Adapter
- ICP-TEMP-Adapter HP / Philips

Device Classification Name:	Device, Monitoring, Intracranial Pressure and Temperature
Classification Panel:	Neurology
CFR Section:	21 CFR §882.1620
Device Class:	Class II
Product Code:	GWM

5. Device Description

The **RAUMEDIC® -ICP-TEMP-Monitoring-System** determines the level and change in intracranial pressure (ICP) by using semi-conductor pressure sensors and temperature monitoring using thermistors.

The NEUROVENT®-TEMP IFD-S and NEUROVENT®-TEMP IFD-R are indicated for use in ventricular pressure and temperature monitoring and cerebrospinal fluid drainage applications. The NEUROVENT®-P-TEMP is indicated for use in parenchymal pressure and temperature monitoring.

The NEUROVENT®-TEMP IFD-S is implanted in the ventricle by using a soft mandrel and the spliceable tunnelling sleeve CH12 (already cleared to market under 510 (k) K112017) or via a RAUMEDIC® - BOLT KIT CH9 (already cleared to market under 510 (k) K112017). The NEUROVENT®-TEMP IFD-R is implanted in the ventricle only by using a rigid mandrel and a RAUMEDIC® - BOLT KIT CH9 (already cleared to market under 510 (k) K112017). The NEUROVENT®-P-TEMP is implanted in parenchyma via a RAUMEDIC® - spliceable tunnelling sleeve CH8 (already cleared to market under 510 (k) K112017) or via a RAUMEDIC® - BOLT KIT CH5 (already cleared to market under 510 (k) K103206).

In addition to the catheters used for pressure and temperature monitoring an ICP-TEMP-cable (already cleared to market under 510 (k) K103206) as well as an ICP-TEMP-Adapter or an ICP-TEMP-Adapter HP / Philips (depending on the type of monitor used) and a zero point module NPS2 x (already cleared to market under 510 (k) K103206) is needed to set up the measuring chain.

"x" depends on the type of patient monitor available in the hospital - there are 20 different references. To measure the pressure and temperature the NPS2 and the temperature plug have to be connected to the monitor.

Device #: _____

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The RAUMEDIC® -ICP-TEMP-Monitoring-System is composed of the following elements:

- NEUROVENT®-TEMP IFD-S
- NEUROVENT®-TEMP IFD-R
- NEUROVENT®-P-TEMP
- ICP-TEMP-Adapter
- ICP-TEMP-Adapter HP / Philips

6. Device Intended Use

The RAUMEDIC® -ICP-TEMP-Monitoring-System is indicated for use in parenchymal and ventricular pressure and temperature monitoring and can be used for the measurement of the intra-cranial pressure (ICP) as well as of the cerebral perfusion pressure (central arterial blood pressure minus ICP) which is the essential pre-requisite for an effective treatment of patients suspected of suffering from intra-cranial pressure increases (such as cranio-cerebral traumas, GCS \leq 8; malignant medial cardiac infarctions; hepatic encephalopathy; SAB Hunt / Hess IV + V; cerebral edema; hydrocephalus) or of patients whose clinical picture may be linked to an increase of the ICP and cerebrospinal fluid drainage applications.

Additional the measurement of the brain temperature allows the direct measurement of the cerebral tissue temperature. This temperature can deviate from the patient's overall body temperature. Measuring the brain's temperature permits episodes of cerebral hypothermia to be detected and also provides additional temperature information during hypothermia treatment.

7. Substantial Equivalence Summary

The RAUMEDIC® -ICP-TEMP-Monitoring-System is substantially equivalent to those of the legally marketed predicate devices, the Camino NeuroCare Intracranial Pressure-Temperature Monitoring Kit, Model 110-4BT and Camino NeuroCare Intracranial Pressure-Temperature Monitoring Kit, Model 110-4HMT, which were cleared to market under 510 (k) K962928 on December 20th 1996 and the RAUMEDIC® -ICP-Monitoring-System which was cleared to market under 510 (k) K103206 on 04th of March 2011 and the RAUMEDIC® -ICP-Monitoring-System ventricular which was cleared to market under 510 (k) K112017 on 11th of October 2011.

In details this means that

- the NEUROVENT®-TEMP IFD-S and the NEUROVENT®-TEMP IFD-R are substantially equivalent to those of the Camino NeuroCare Intracranial Pressure-Temperature Monitoring Kit, Model 110-4HMT and RAUMEDIC® -ICP-Monitoring-System ventricular.
- the NEUROVENT®-P-TEMP is substantially equivalent to those of the Camino NeuroCare Intracranial Pressure-Temperature Monitoring Kit, Model 110-4BT and the RAUMEDIC® -ICP-Monitoring-System.

For further information see device comparison tables attached.



Based on performance testing and the available information concerning the referenced comparison device, the RAUMEDIC® -ICP-TEMP-Monitoring-System is equivalent in that:

- The devices have the same intended use and indication for use.
- The devices are made of the same materials or substantially equivalent materials.
- The devices have equivalent form, function, procedures and features.
- Performance characteristics are suitable for designated indications for use

Based on this, the anticipated clinical performance of the RAUMEDIC® -ICP-TEMP-Monitoring-System is equivalent to the referenced systems.

8. Device Testing

Biocompatibility studies were conducted per ISO 10993 standard and have demonstrated that the materials used to manufacture the RAUMEDIC® -ICP-TEMP-Monitoring-System are safe for its intended use.

In addition, the mentioned catheters were subjected to extensive performance testing. Results of the testing showed that the catheter designs are safe for their intended uses.

Finally, the manufacturing process of the RAUMEDIC® - ICP-TEMP- Monitoring - System complies with the United States Food and Drug Administration and European Standards for the manufacturing of medical devices.

Device #: _____

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See attachment 2: Device comparison tables (complete 5 pages).

Table 1

Feature	RAUMEDIC® ICP-TEMP- MONITORING-SYSTEM	RAUMEDIC® ICP-MONITORING- SYSTEM (K103206)	RAUMEDIC® ICP-MONITORING- SYSTEM ventricular (K112017)	SE?
Trade Name	NEUROVENT®-P-TEMP, NEUROVENT®-TEMP-IFD-S, NEUROVENT®-TEMP-IFD-R	NEUROVENT®-P, NEUROVENT®-P-C	NEUROVENT®, NEUROVENT®-IFD-S, NEUROVENT®-IFD-R	N/A
Indication for Use	SAME	SAME	SAME	YES
Anatomical Site- Catheter	Brain parenchyma/ ventricle	Brain parenchyma	Brain ventricle	YES
ICP-Sensor Design Catheter	Miniatuer transducer	Miniatuer transducer	Miniatuer transducer	YES
Temperature-Sensor Design Catheter	Thermistor	—	—	NO — see SE-List with predicate devices: Camino NeuroCare Intracranial Pressure-Temperature Monitoring Kit
Temperature Range	25°C - 45°C	—	—	NO — see SE-List with predicate devices: Camino NeuroCare Intracranial Pressure-Temperature Monitoring Kit
Transducer Location	Catheter Tip	Catheter Tip	Catheter Tip	YES
Non-fluid coupling Catheter	YES	YES	YES	YES
Single-use-Catheter	YES	YES	YES	YES
Pressure Range	-50 to +250 mmHg	-50 to +250 mmHg	-50 to +250 mmHg	YES

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Feature	RAUMEDIC® ICP-TEMP- MONITORING-SYSTEM	RAUMEDIC® ICP-MONITORING- SYSTEM (K103206)	RAUMEDIC® ICP-MONITORING- SYSTEM ventricular (K112017)	SE?
Zero Point Stability Catheter	Less than 1mmHg during first 24 hours Less than 2mmHg during the first 7 days	Less than 1mmHg during first 24 hours Less than 2mmHg during the first 7 days	Less than 1mmHg during first 24 hours Less than 2mmHg during the first 7 days	YES
Sensitivity System	5 µV/V/mmHg on the monitor side	5 µV/V/mmHg on the monitor side	5 µV/V/mmHg on the monitor side	YES
Maximum pressure Catheter	1,250 mmHg	1,250 mmHg	1,250 mmHg	YES
Sterilization process	With Ethylene Oxide	With Ethylene Oxide	With Ethylene Oxide	YES
Bolt	Bolt with compression cap	Bolt with compression cap	Bolt with compression cap	YES
Spliceable tunnelling sleeve	Spliceable Tunnelling Sleeve with Trocar	—	Spliceable Tunnelling Sleeve with Trocar	YES
TEMP-Adapter	ICP-TEMP-Adapter ICP-TEMP-Adapter HP / Philips	—	—	NO — see SE-List with predicate devices: Camino NeuroCare Intracranial Pressure-Temperature Monitoring Kit
Product Code	GWM	GWM	GWM	YES
Registration #	Pending	K103206	K112017	N/A
Applicant	RAUMEDIC AG Hermann-Staudinger-Str. 2 95233 Helmbrechts Germany	RAUMEDIC AG Hermann-Staudinger-Str. 2 95233 Helmbrechts Germany	RAUMEDIC AG Hermann-Staudinger-Str. 2 95233 Helmbrechts Germany	N/A

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Table 2

Feature	RAUMEDIC® ICP-TEMP- MONITORING-System	Camino® NeuroCare™ Intracranial Pressure and Temperature Monitoring Kit	Camino® NeuroCare™ Intracranial Pressure and Temperature Monitoring Kit	SE?
Trade Name	NEUROVENT® P-TEMP, NEUROVENT® TEMP-IFD-S, NEUROVENT® TEMP-IFD-R	Micro-Ventricular Pressure-Temperature Monitoring Kit (110-4HMT)	Parenchymal Pressure-Temperature Monitoring Kit (110-4BT)	N/A
Indication for Use	SAME	SAME	SAME	YES
Anatomical Site-Catheter	Brain parenchyma/ventricle	Brain ventricle	Brain parenchyma	YES
ICP-Sensor Design Catheter	Miniatuer transducer	Optical reflector	Optical reflector	NO - see SE-List with predicate devices: RAUMEDIC® ICP-MONITORING- SYSTEM and RAUMEDIC® ICP-MONITORING- SYSTEM ventricular
Temperature-Sensor Design Catheter	Thermistor	Thermistor	Thermistor	YES
Temperature Range	25°C - 45°C	30°C - 40°C	30°C - 40°C	NO - see SE-discussion 1 below table
Transducer Location	Catheter Tip	Catheter Tip	Catheter Tip	YES
Non-fluid coupling Catheter	YES	YES	YES	YES
Single-use-Catheter	YES	YES	YES	YES

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Feature	RAUMEDIC® ICP-TEMP- MONITORING-System	Camino® NeuroCare™ Intracranial Pressure and Temperature Monitoring Kit	Camino® NeuroCare™ Intracranial Pressure and Temperature Monitoring Kit	SE?
Pressure Range	-50 to +250 mmHg	-10 to +250 mmHg	-10 to +250 mmHg	NO - see SE-List with predicate devices: RAUMEDIC® ICP-MONITORING- SYSTEM and RAUMEDIC® ICP-MONITORING- SYSTEM ventricular
Zero Point Stability Catheter	Less than 1 mmHg during first 24 hours Less than 2 mmHg during the first 7 days	Less than 2 mmHg during first 24 hours Less than 1 mmHg per day during the first 5 days	Less than 2 mmHg during first 24 hours Less than 1 mmHg per day during the first 5 days	NO - see SE-List with predicate devices: RAUMEDIC® ICP-MONITORING- SYSTEM and RAUMEDIC® ICP-MONITORING- SYSTEM ventricular
Sensitivity System	5 µV/V/mmHg on the monitor side	5 µV/V/mmHg on the monitor side	5 µV/V/mmHg on the monitor side	YES
Maximum pressure Catheter	1,250 mmHg	1,250 mmHg	1,250 mmHg	YES
Sterilization process	With Ethylene Oxide	With Ethylene Oxide	With Ethylene Oxide	YES
Bolt	Bolt with compression cap	Bolt with compression cap	Bolt with compression cap	YES

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Feature	RAUMEDIC® ICP-TEMP-MONITORING-System	Camino® NeuroCare™ Intracranial Pressure and Temperature Monitoring Kit	Camino® NeuroCare™ Intracranial Pressure and Temperature Monitoring Kit	SE?
Spliceable tunnelling sleeve	Spliceable Tunnelling Sleeve with Trocar	—	—	NO — see SE-List with predicate devices: RAUMEDIC® ICP-MONITORING- SYSTEM and RAUMEDIC® ICP-MONITORING- SYSTEM ventricular
TEMP-Adapter	ICP-TEMP-Adapter ICP-TEMP-Adapter HP / Philips	ICT-XX (XX stands for specific Monitor-Type)	ICT-XX (XX stands for specific Monitor-Type)	YES
Product Code	GWM	GWM	GWM	YES
Registration #	Pending	K962928	K962928	N/A
Applicant	RAUMEDIC AG Hermann-Staudinger-Str. 2 95233 Helmbrechts Germany	RAUMEDIC AG Hermann-Staudinger-Str. 2 95233 Helmbrechts Germany	RAUMEDIC AG Hermann-Staudinger-Str. 2 95233 Helmbrechts Germany	N/A

1) The temperature range of the RAUMEDIC® ICP-TEMP-MONITORING-System fully includes the temperature range of the Camino® NeuroCare™ Intracranial Pressure and Temperature Monitoring Kit and additionally fulfills the regulatory requirements according to the ASTM E112 standard. Due to these facts, the RAUMEDIC® ICP-TEMP-MONITORING-System does not raise any additional concerns regarding safety and effectiveness in the point of temperature range.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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RAUMEDIC AG
c/o Mr. Olaf Teichert
TUV SUD America, Inc.
1775 Old Highway 8 NW
New Brighton, MN 55112-1891

APR 11 2012

Re: K120252

Trade/Device Name: Raumedic ICP Monitoring System
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: January 24, 2012
Received: January 27, 2012

Dear Mr. Teichert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

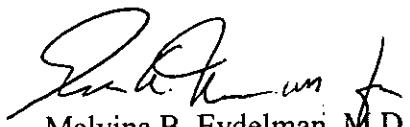
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



RAUMEDIC®
Lifeline to Health

K120252

Indications for Use

510(k) Number (if known): K_____

Device Name: Device, Monitoring, Intracranial Pressure and Temperature

Indications for Use:

The RAUMEDIC®-ICP-TEMP-Monitoring-System is indicated for use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the parenchyma and in the ventricle and cerebrospinal fluid drainage applications.

Use of the parenchymal and ventricular intracranial pressure monitoring kit with bolt is contra-indicated in children under one year old.

The RAUMEDIC® catheters are MR Unsafe.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use X
(Per 21 CFR 801.109)


(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K120252